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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT PAPER NUMBER

1743

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/538,354

Applicant(s)

SWIERKOWSKI, STEFAN P.

Examiner

ALEX NOGUEROLA

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15, 18, 19, 29-31, 33 and 34 is/are rejected.
- 7) ☒ Claim(s) 14, 16, 17, 20-28 and 32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 24 September 2002 is: a) ☐ approved b) ☒ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the cross-load array of Claim 1 wherein the functionally identical channels have identical lengths from the injection point to the sample well, waste well, cathode, and anode must be shown or the feature canceled from Claim 32. No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

2. The proposed drawing corrections, filed on September 24, 2002 have been not been approved. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance. There are two figures labeled "Figure 1". One of these figures should be labeled Figure 1A, the other Figure 1B. The relabeling of the three Figure 2's as Figures 2A-2C is acceptable. Several sample wells in Figure 3 have been relabeled 1-8; however, according to the specification numerals 1-8 refer to channels (page 8, lines 3-6 and lines 18-20). Also several sample wells are labeled with two numbers. Has "10" been indicated to be an injection point in the specification?

Claim Objections

3. Claims 13, 28, 31, and 32 are objected to because of the following informalities:

- a) Claim 13: the first occurrence of “from” in line two should be -- form --;
- b) Claim 28, line 2: “well” should be -- wells --; and
- c) Claims 31 and 32: “have” should be -- has --; and
- d) Claim 32, line 2: “a” should be -- the --.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. Claims 3, 29, and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

- a) Claim 3, lines 2-3: “to define ... holes.” should be replaced with -- consisting of wells having substantially circular holes, wells having substantially tapered holes, and wells having holes. --;
- b) Claim 29: how is Claim 1 further limited by this claim as an array of functionally identical channels entails at least one pair of functionally identical channels; and
- c) Claim 32, lines 1-2: “array of” should be deleted.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-5, 9-13, 15, 18, 19, 29-31, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. (US 6,143,152).

Addressing Claims 1 and 29, Simpson et al. teach a microchannel cross load array (the abstract), comprising

a cathode (120 and 130 in Figure 1 and "CATHODE" in Figure 2);

an array of sample wells (B wells and C wells in Figures 1 and 2);

an array of waste wells (D wells in Figures 1 and 2), the sample wells comprising four times the number of waste wells;

an anode (180 in Figure 1 and "ANODE" in Figure 2), and

an array of functionally identical channels (unlabeled in Figure 1 but they correspond to channels **202** and **222** in Figure 2), each channel having an injection point connected directly to only two wells of the array of sample wells (Figures 1 and 2), connected directly to only one well of the array of waste wells (Figures 1 and 2), connected directly to the cathode (Figures 1 and 2), and directly connected to the anode (Figures 1 and 2).

Claim 1 requires that an injection point is connected directly to only one sample well. As stated above, in Simpson et al. the injection points are each connected directly to two sample wells. This is so two different samples may be simultaneously analyzed in each separation channel. If only one sample is to be analyzed at a time, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have each injection point connected directly to only one sample well because then the array could be more compact as fewer sample wells and channels will be needed. In other words, the number of sample wells connected directly to each injection point will be primarily determined by the number of samples to be run through each separation channel.

Addressing Claim 2, **120** and **130** in Figure 1 are common cathode slots. **180** in Figure 1 is a common anode slot.

Addressing Claim 3, circular holes are suggested by Figures 1 and 2.

Addressing Claim 4, waste wells defining substantially circular holes are suggested by elements **D** in Figures 1 and 2.

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Addressing Claim 5, sample wells defining substantially circular holes are suggested by elements **B** and **C** in Figures 1 and 2. Waste wells defining substantially circular holes are suggested by elements **D** in Figures 1 and 2.

Addressing Claim 9, as seen in Figure 1 the cross-load array has biaxial symmetry and orthogonal rows and columns.

Addressing Claim 10, from Figures 1 and 2 there does not appear to be a difference in shape between any of the channels.

Addressing Claim 11, as seen in Figures 1 and 2 the array has mirror-image symmetry along two axes and each subset of wells has mirror-image symmetry along two axes.

Addressing Claim 12, as seen in Figures 1 and 2 the flow path from the injection point to the cathode is longer than from an injection point to the waste well.

Addressing Claim 13, as seen in Figure 1 the flow paths from the injection points to the cathode is symmetrical with the flow paths from the injection point to the waste wells.

Addressing Claim 15, as seen in Figure 1 the array of sample wells is located in a plurality of rows.

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Addressing Claim 18, if one rotates Figure 1 ninety degrees one may see that cathode **120**, for example, is a common bias to several sample wells in the top row of sample wells.

Addressing Claim 19, if one rotates Figure 1 ninety degrees one may see that cathode **120** or anode **180**, for example, is a common bias to several waste wells in the top row of waste wells.

Addressing Claim 30, a plurality of pairs of functionally identical channels is clearly seen in Figure 1.

Addressing Claim 31, as seen in Figures 1 and 2 each pair of functionally identical channels has a common waste well.

Addressing Claim 33, as seen in Figures 1 and 2 each waste well is aligned with at least one sample well.

Addressing Claim 34, as seen in Figures 1 and 2 each waste well is offset at least one sample well.

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8. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. (US 6,143,152) as applied to claims 1-5, 9-13, 15, 18, 19, 29-31, 33, and 34 above, and further in view of Zanzucchi et al. (US 5,846,396).

Simpson et al. teach a microchannel cross load array (the abstract), comprising
a cathode (120 and 130 in Figure 1 and "CATHODE" in Figure 2);
an array of sample wells (B wells and C wells in Figures 1 and 2);
an array of waste wells (D wells in Figures 1 and 2), the sample wells comprising four times the number of waste wells;
an anode (180 in Figure 1 and "ANODE" in Figure 2), and
an array of functionally identical channels (unlabeled in Figure 1 but they correspond to channels 202 and 222 in Figure 2), each channel having an injection point connected directly to only two wells of the array of sample wells (Figures 1 and 2), connected directly to only one well of the array of waste wells (Figures 1 and 2), connected directly to the cathode (Figures 1 and 2), and directly connected to the anode (Figures 1 and 2).

Claim 1 requires an injection point connected directly to only one sample well. As stated above, in Simpson et al. the injection points are each connected directly to two sample wells. If the array will only be used to analyze one sample, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have the injection points connected directly to only one sample well because then the array could be more compact as fewer sample wells and channels will be needed. The number of sample wells will be clearly primarily determined by the number of samples to be run.

Simpson et al. also do not teach wells defining square holes. Microfluidic systems having wells defining square holes were known at the time of the invention, as shown by Figure 1 of Zanzucchi et al. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use wells defining square holes as taught by Zanzucchi et al., whether as sample wells, waste wells, or both, in the invention of Simpson et al. because this will allow the wells to be densely packed together while maximizing the cross-sectional area of the well (a square has a greater area than a circle whose diameter is equal in length to the length of a side of the square).

Allowable Subject Matter

9. Claims 14, 16, 17, 20-28, and 32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims:

a) Claims 14 and 20: as seen in Figure 1 of Simpson et al. the lengths of the flow paths from the injection points to the cathode is longer than the lengths of the flow path from the injection points to the waste wells. There is no obvious way to have the all of these lengths the same; to do so would require a significant reconfiguration of the wells and channels;

b) Claim 16: as seen in Figure 1 the pitch between channels adjacent the anode is much smaller than the twice the pitch between adjacent sample wells in each row;

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c) Claim 17 depends from Claim 16;

d) Claims 21-28 depend directly or indirectly from Claim 20; and

e) Claim 32: as seen in Figure 1 of Simpson et al. the lengths are not the same for the flow paths from each injection point to its related cathode, anode, sample well, and waste well. There is no obvious way to have the all of these lengths the same; to do so would require a significant reconfiguration of the wells and channels;

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (703) 305-5686. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JILL WARDEN can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Alex Noguera

Alex Noguera
January 12, 2003

Jill Warden
Jill Warden
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